

## REMARKS

Claim 1 is pending in the application and stands rejected. New Claim 6 has been added. Support for the new Claim 6 is found in the Specification, for example, on page 3, lines 11-21; page 8, lines 16-30; page 9, line 18, to page 21, line 7. The Specification has been amended to correct a typographical error. No new matter has been added. The applicants respectfully request reconsideration of the pending claims in view of the remarks below.

### Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner has rejected Claim 1 under 35 U.S.C. § 112, first paragraph, as not being supported by an adequate written description. According to the Examiner, the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus of genes “whose expression is upregulated in infective salivary gland sporozoites and whose function is not required for entry into host hepatocytes.” The applicants respectfully disagree.

Genes having the claimed common attributes are described in detail in the Specification, and were published by the applicants’ research groups before the priority date of this application (see Specification, page 4, lines 8-10; and cited references 11 and 12, incorporated into the application by reference on page 22, lines 2-3). Moreover, the disclosure provides a detailed description of methods that may be used to identify additional genes having these common attributes using techniques that are well-known in the art (see, for example, Specification, page 3, line 11, to page 5, line 20; page 8, line 16, to page 9, line 3.)

Furthermore, the Federal Circuit has recently clarified its ruling in *The Regents of the University of California v. Eli Lilly. Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). In this case, the Federal Circuit held that the disclosure for a poxvirus vaccine satisfied the written description requirement even though the specification at issue failed to give examples involving poxviruses or provide “essential regions” or structure of any poxvirus. The Court stated that “it

is the binding precedent of this court that *Eli Lilly* does *not* set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art.” *Id.* At 1367 (emphasis in original). Instead, the Federal Circuit held that “where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here “essential genes”), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences.” *Id.* at 1368 (internal footnote omitted).

Finally, the applicants note that the Examiner had previously approved essentially identical claim language in related applications that have issued as U.S. Patent No. 7,261,884 and U.S. Patent No. 7,122,179. Accordingly, the applicants respectfully request the withdrawal of this ground of rejection.

#### Nonstatutory Obviousness-Type Double Patenting

The Examiner has rejected Claim 1 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 7,261,884 and U.S. Patent No. 7,122,179, respectively.

Without acquiescing in the Examiner’s position, the applicants are submitting a terminal disclaimer over U.S. Patent Nos. 7,261,884 and 7,122,179. Withdrawal of the rejection is respectfully requested.

#### New Claim 6

New Claim 6 is a live *Plasmodium* organism that is genetically engineered to disrupt a gene whose expression is up-regulated in liver-stage parasites and whose function is not required for entry into host hepatocytes. Support for new Claim 6 may be found throughout the Specification, for example, on page 3, lines 11-21; page 8, lines 16-30; page 9, line 18, to

page 21, line 7. For the same reasons provided above for Claim 1, applicants submit that new Claim 6 is supported by an adequate written description.

Conclusion

In view of the foregoing amendments and remarks, the pending claims are believed to be in condition for allowance. If any issues remain that can be expeditiously addressed in a telephone interview, the Examiner is encouraged to contact the undersigned representative.

Respectfully submitted,

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